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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,372	BERUBE ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al. (US 5,810,811; "Yates") in view of Hooven et al. (US 6,517,536; "Hooven"). Yates discloses a clamp accessory capable of having an ablation device removably positioned therein, the clamp accessory comprising a first and second elongated jaw, the first elongated jaw having a recess in an inner surface thereof adapted to slidably receive the ablation device therein, a hinge structure operably attaching the first and second jaw members for relative rotation between an open and closed configuration along an axis for selectively effecting closure of the first and second jaw members to operatively engage the ablation device upon a target tissue disposed between the first and second jaw members, and a transmurality system disposed on one of the members (fig. 12 or 14) and adapted for monitoring the transmurality of an ablation lesion formed therein by the ablation device disposed within the recess of the first jaw member (col. 9 ll. 13-19, 31-45). Although Yates discloses using these electrodes to ablate tissue as well as for monitoring the transmurality of the ablation lesion based on tissue impedance readings, the electrodes are capable of monitoring the transmurality of an ablation lesion formed by a different ablation tool by sending an electrical signal through the tissue which is monitored by the impedance indicators. It is noted that the ablation device is recited only in functional language and therefore the device of Yates must only be capable of engaging an ablation device within the recess of the first jaw member to meet the limitations of the claim. Yates fails

to disclose that the hinge structure allows for rotation around an axis substantially aligned with the elongated direction of the jaw members.

3. However, Hooven teaches such a configuration. In particular, the elongated jaws of Hoove turn such that they are perpendicular to the longitudinal axis of the device (figs. 28, 29). Jaws that curve away from the longitudinal axis are well known in the art and are used to improve visibility for the surgeon as well as making it easier to reach around anatomical structures to grab the desired piece of tissue. Therefore, it would have been obvious to one skilled in the art to modify the device of Yates et al. to curve the jaws as made obvious by Hooven in order to improve visibility and tissue grasping capabilities of the device. Adding a curve to the jaws of Yates as taught by Hooven will result in jaws that are elongated in a direction perpendicular to the longitudinal axis of the device. The rotational axis of the jaws (around the hinge) is also perpendicular to the longitudinal axis of the device.

4. Regarding claim 21, Yates discloses two electrodes disposed on opposite sides of the recessed inner surface of the first jaw member to selectively transfer electrical signals therebetween through the target tissue (see fig. 12 or 14).

5. **Claims 22 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates in view of Hooven as applied to claim 1 above, and further in view of Francischelli et al. (US 6,584,360; "Francischelli"). Yates in view of Hooven discloses the claimed invention except for a layer of liquid crystals that exhibits a visible color change at a given temperature.

6. Francischelli discloses that such indicators on ablation tools that access transmurality of an ablation lesion are well known. In particular, Francischelli discloses positioning a sensing pad on the side of tissue opposite the side the ablation tool is being applied and the pad senses the temperature changes as the tissue is ablated. This pad has incorporated therein a plurality of temperature-sensing liquid crystals and may be used in conjunction with a color scheme in

which each color indicates a temperature (col. 3, ll. 35-52; col. 7 ll. 60-col. 8 ll. 17). It would have been obvious to one skilled in the art to further modify Yates to include such an indicator on the second jaw member, since this jaw member is opposite the ablation device, so that the transmurality of an ablation lesion may be monitored by the user. Although not expressly taught by Francischelli, it would have also been obvious to provide a viewing means for the pad such as a transparent area or window on the second jaw so that the pad can be both in contact with the tissue and visible to the user through the second jaw.

7. **Claims 1, 21, 24, and 25** are also rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al. (US 6,053,933; "Balazs") in view of Foley et al. (US 6,663,622; "Foley") and Hooven. Balazs discloses a clamp accessory for removable positioning therein of an ablation device, the clamp accessory comprising a first and second elongated jaw (1, 2), the first jaw (2) having a recess in an inner surface thereof adapted to slidably receive the ablation device therein, and a hinge structure operably attaching the first and second jaw members for relative rotation between open and closed configurations (figs. 1-4). Balazs discloses positioning an ablation device (7) within the recess (col. 5 ll. 37- 44, esp. 43-45). Balazs fails to teach the following which is taught by Foley and Hooven.

8. Foley teaches including a transmurality system disposed on one of the jaw members of a clamp including an electrode on either side of a recess through which an ablation device is passed (see fig. 1; probe 22, electrodes 16). The electrodes are advantageous because they can be used to monitor the transmurality of an ablation lesion formed by the ablation instrument passed therethrough (col. 9 ll. 50-64). It would have been obvious to one skilled in the art to employ at least two electrodes disposed on either side of the recess in jaw 2 of Balazs, which holds an ablation device in order to be able to monitor the transmurality of the ablation lesion.

9. Hooven teaches having jaws elongated in a direction aligned with the axis of rotation of the jaws about a hinage. In particular, the elongated jaws of Hooven turn such that they are perpendicular to the longitudinal axis of the device (figs. 28, 29). Jaws that curve away from the longitudinal axis are well known in the art and are used to improve visibility for the surgeon as well as making it easier to reach around anatomical structures to grab the desired piece of tissue. Therefore, it would have been obvious to one skilled in the art to modify the device of Balazs to curve the jaws as made obvious by Hooven in order to improve visibility and tissue grasping capabilities of the device. Adding a curve to the jaws of Balazs as taught by Hooven will result in jaws that are elongated in a direction perpendicular to the longitudinal axis of the device. The rotational axis of the jaws (around the hinge) is also perpendicular to the longitudinal axis of the device.

10. Regarding claim 25, see col. 6, ll. 12-15 of Foley.

11. Regarding claim 24, Balazs in view of Foley and Hooven does not disclose protrusions on the inside surface of the recess on the first jaw for contacting an ablation device therein. However it is well known in the art to provide grooves or projections on the surface of recesses that receive another instrument in order to center the inner instrument relative to the recess and such a modification would have been within the purview of one skilled in the art since an ablation tool (7) is meant to be housed in the recess (for example, see col. 6, ll. 14-16 of US 4,881,550 to Kothe).

12. **Claims 22 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs in view of Foley and Hooven as applied to claim 1 above, and further in view of Francischelli et al. (US 6,584,360; “Francischelli”). Balazs in view of Foley and Hooven discloses the claimed invention except for a layer of liquid crystals that exhibits a visible color change at a given temperature.

13. Francischelli discloses that such indicators on ablation tools that access transmurality of an ablation lesion are well known. In particular, Francischelli discloses positioning a sensing pad on the side of tissue opposite the side the ablation tool is being applied and the pad senses the temperature changes as the tissue is ablated. This pad has incorporated therein a plurality of temperature-sensing liquid crystals and may be used in conjunction with a color scheme in which each color indicates a temperature (col. 3, ll. 35-52; col. 7 ll. 60-col. 8 ll. 17). It would have been obvious to one skilled in the art to further modify Balazs to include such an indicator on the second jaw member, since this jaw member is opposite the ablation device, so that the transmurality of an ablation lesion may be monitored by the user. Although not expressly taught by Francischelli, it would have also been obvious to provide a viewing means for the pad such as a transparent area or window on the second jaw so that the pad can be both in contact with the tissue and visible to the user through the second jaw.

14. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs in view of Foley and Hooven as applied to claim 25 above, and further in view of Gold et al. (US 2003/0212435; "Gold"). Balazs in view of Foley and Hooven discloses the claimed invention substantially. Hooven makes obvious the use of a plurality of bending elements disposed within the first jaw for altering its malleable characteristics. Balazs fails to disclose that one of these bending elements has different bending characteristics along its length.

15. Gold teaches that it is well known to design jaws that have varying degrees of flexibility and stiffness along their lengths (par. 19). It would have been obvious to one skilled in the art to vary the bending characteristics of the bending elements along their length such that the jaw has varying degrees of flexibility along its length because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, including known jaw

material characteristics. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Response to Arguments

16. Applicant's arguments filed 8/15/2008 have been fully considered but they are not persuasive. In response to applicant's argument that Yates in view of Hooven fail to disclose housing an ablation device within a recess of the jaw, it is noted that the ablation device is not claimed as part of the clamp accessory (rather, it appears in functional language) and the clamp accessory must only be capable of receiving an ablation device within a recess of the jaw. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

17. In response to applicant's arguments against the references of Balazs, Foley, and Hooven individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 11/4/2008

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731